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November 13, 2024

**By ECF**

Hon. Douglas E. Arpert, U.S.M.J. (Ret.)  
Three Gateway Center  
100 Mulberry Street  
15th Floor  
Newark, New Jersey 07102

Re: **United States ex rel. Silbersher v. Janssen Biotech Inc., et al.,  
Civil Action No. 19-12107 (MEF-SDA)**

Dear Judge Arpert:

Defendants respectfully submit this letter to briefly address certain factual inaccuracies in Relator's Responses (ECF Nos. 403, 406) to Defendants' letters asking the Court (1) to compel Relator's compliance with Rule 26; and (2) to extend Defendants' expert discovery deadline commensurate with the time that Relator has failed to comply with Rule 26.

**First**, Relator acknowledges that an extension is appropriate; his only quarrel is on the appropriate length. Relator proposes an extension to January 20, 2025, ECF 406 at 11, but refuses to consent to Defendants' request. That request is simple: the deadline should be extended such that Defendants have four months to prepare their expert reports from the date that Relator comes into compliance with Rule 26, which is what the Scheduling Order approved by Judge Kiel contemplated. ECF 213 at 2. Relator's failure to make the disclosures required by Rule 26 when he served his expert reports, and his persistent delay in curing those deficiencies since, has deprived Defendants of the time afforded to them under that order.

Relator misrepresents the time the Scheduling Order provided to the parties to prepare expert reports. Relator asserts that the scheduling order gave Relator only two months to prepare his expert reports whereas Defendants received six. Not so. Relator bears the burden of proof in this case, and the Scheduling Order necessarily contemplated that Defendants' expert reports would be responsive to whatever theories Relator chose to advance in his expert reports. Relator has been free to work on his reports since the start of this case, and his privilege log reflects he has been doing so for nearly seven years. *See* Ex. A, Relator's Privilege Log at Lines 40–45. By contrast, Defendants could not meaningfully begin work on responding to Relator's experts until they actually received the expert reports. That task has become even more daunting because, as Defendants' letter explained, Relator's expert reports raise multiple new theories, subjects, and

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contentions not pled in the Complaint. *See* ECF 399 at 3–7.

**Second**, Relator mischaracterizes the deficiencies in his expert reports, each of which failed to comply with Rule 26. For example, Relator argues that he merely failed to provide a few “pincites” for materials relied upon by his experts. This is not accurate. Relator’s disclosures were deficient from the start: they disclosed only sources “relied upon” by the experts, not sources “considered,” as Rule 26 requires. Relator has also excluded materials “screened” by the experts from their disclosures, a step that has no basis in law. *See* ECF 391 at 5–7. And, to the extent Relator’s experts omitted “pincites,” in many instances those references were to books hundreds of pages long. It is not the receiving party’s job to guess which part of such voluminous sources are actually being cited.

Relator refused to take any steps to remedy these deficiencies until Defendants filed their motion to compel, despite Defendants’ attempts to meet and confer for over two months. Since Defendants filed their motion, starting on November 4, 2024, Relator has now served amended reports for six experts. The amended reports add significant new information not previously disclosed by Relator. For example, Dr. Mark Ratain, identifies at least 150 new documents not specifically described in his prior report. Similarly, for Sean Tu, Relator has now disclosed more than 40 new sources not disclosed in the initial expert report.<sup>1</sup> And five of Relator’s experts (Singer, Clark, Bahr, Hyman, and Femia) disclose nearly a dozen or more new sources of information “considered” in preparing their expert reports. These are significant omissions. They would not have been disclosed but for Defendants’ attempts to bring Relator into compliance with Rule 26, and Defendants’ period for preparing responsive expert reports should be extended as a result of Relator’s late disclosures and his still-persisting failure to cure other defects in his expert reports.

**Third**, Relator attempts to shift the blame for his own misdeeds to Defendants. For example, Relator faults Defendants for not seeking an extension sooner. That makes no sense. The Local Rules require that parties meet and confer before seeking the Court’s intervention. Defendants did just that, and only sought the Court’s intervention when it became apparent that Relator was refusing to budge.

Relator also wrongly accuses Defendants of ineffectively using fact discovery. But Relator repeatedly refused to provide information during fact discovery. For instance,

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<sup>1</sup> Notably, Relator refused to provide a revised report, signed by Professor Tu, disclosing these additional sources. Rather, Relator’s counsel emailed Defendants with a list of these additional references, some of which were not even published until *after* the Scheduling Order’s deadline for Professor Tu’s report to be served. *See, e.g.*, Ex. B, N. Herrera Emails at 5 (citing Lattouf et al., *Side effect management algorithms for niraparib/abiraterone acetate in prostate cancer*, *Can. J. Urol* 31(5):11977–85 (Oct. 2024)). The next day, Relator’s counsel then emailed Defendants an updated list of references that purported to withdraw those after-the-deadline sources. *Id.* at 1–3. These repeated amendments underscore the need for Relator to serve final reports, signed by the experts themselves, making all the disclosures required by Rule 26, and further illustrates the need for an extension for Defendants to respond to disclosures Relator should have made when his expert reports were originally due.

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Defendants served multiple interrogatories requesting that Relator describe the metes and bounds of his claims. He failed adequately to comply, Defendants twice moved to compel responses, and Relator waited until the last day of fact discovery to dump new (and largely repetitive) interrogatory responses onto Defendants. Defendants also sought similar information during Relator's deposition; yet, Relator refused to answer certain questions, claiming they were topics for expert discovery.<sup>2</sup>

In sum, Relator's conduct has deprived Defendants of a meaningful opportunity to rebut his case. For these reasons, and the reasons in Defendants prior letters, this Court should grant Defendants' request for an extension and for an order directing Relator to serve signed, complete reports for each expert disclosing all material the expert considered, as required by Rule 26.

Respectfully yours,

*/s/ Jeffrey J. Greenbaum*

Jeffrey J. Greenbaum

cc: Counsel of Record (via ECF and Email)

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<sup>2</sup> See, e.g., Ex. C, Silbersher Depo. Tr. 115: 9-25 ("Q: My question was, do you have an understanding of how long on average it took the FDA to approve an ANDA in the 2013 to 2016 time period? Mr. Herrera: Objection, form, and to the extent that this question calls for expert testimony, we further object that it's premature.").